UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO

GARY KROL AND AND KASHA KROL, HIS WIFE,	
Plaintiffs,	**CASE NO:** 2:09 cv 1082
v.	**JUDGE** JUDGE SARGUS MAGISTRATE JUDGE KEMP
ADVANCED INFUSION, INC., HOSPIRA, INC., and ABBOTT LABORATORIES,	**COMPLAINT AND JURY DEMAND**
Defendants.	

PLAINTIFFS' FIRST AMENDED COMPLAINT AND JURY DEMAND

NOW COMES the Plaintiffs, Gary and Kasha Krol, by and through their attorneys, and for their causes of action, sue the Defendants, and allege as follows:

PREAMBLE

1. Pain pumps are medical devices that surgeons used to manage post-operative pain. Orthopedic surgeons used pain pumps after surgery to deliver, by way of a catheter, continuous doses of pain relief anesthetic for several days directly into the shoulder.

2. The pumps first used in the 1990s had limited amounts of anesthetic, and surgeons placed the pain pump catheter in the muscle or outside the shoulder joint. Over the years, however, the manufacturers increased the anesthetic capacity of the pumps (high volume), and with the knowledge and encouragement of the pain pump manufacturers, surgeons began to insert the catheter directly into the shoulder joint space.

3. Continuous injection of these anesthetics directly into the shoulder joint can cause serious and permanent damage to the shoulder joint cartilage. The damage occurs when the

anesthetic kills the chondrocytes (cartilage cells) and causes cartilage to degenerate progressively. Patients injured by pain pumps develop a condition called "chondrolysis," which is the complete or nearly complete loss of cartilage in the shoulder joint. It is an irreversible, disabling, and extremely painful condition. These patients typically require additional surgeries, including complete shoulder joint replacement. As written in the medical literature, "the prognosis for these shoulders is grim."[1]

4. The pain pump companies manufactured and marketed these devices without doing a single study to determine the safety of high-volume pain pumps, or what damage could be caused when physicians placed the catheter directly into the shoulder joint space. The manufacturers of the anesthetics, similarly, did nothing to investigate whether the continuous infusion of their drugs into shoulder joint spaces was harmful. Instead, the pain pump manufacturers encouraged orthopedic surgeons to use the pumps and anesthetics, in tandem, in an untested and dangerous manner.

5. Indeed, the pain pump manufacturers sought approval from the Food and Drug Administration (FDA) for the placement of the catheter in the shoulder joint space beginning in the late 1990s. For lack of safety information, the FDA *rejected* their applications for orthopedic and intra-articular placement. Yet, the pump manufacturers chose not to advise physicians about these dangers, not to advise patients of these risks, not to tell physicians that their FDA applications were rejected, and continued to sell and market these pumps with reckless indifference – all to the detriment of thousands of patients generally, and the Plaintiff, Deborah L. Mayle, in particular.

6. Beginning in 2004, multiple scholarly studies were published demonstrating the toxic effects of pain pump anesthetics on shoulder cartilage. By late 2005 and early 2006, the

[1] Petty, D.H. *et al.*, *Glenohumeral Chondrolysis After Shoulder Arthroscopy*, Am. J. Sports Med. 32:(2)509 (2004).

pain pump industry knew that Dr. Charles L. Beck, an orthopedic surgeon, was reporting to the scientific community some very disturbing findings. He found a significant number of his shoulder patients developed chondrolysis following intra-articular placement of a pain pump catheter, and he associated these injuries with the use of intra-articular pain pumps.

7. Had the defendant manufacturers conducted those studies that the FDA required back in the 1990s, as they were obligated to do, they would readily have determined that exposure to pain pump anesthetics over time in the shoulder is exceedingly dangerous and contraindicated. Had they performed the appropriate tests timely, Mr. Krol's physician would not have used pain pumps in the joint space, and Mr. Krol would not have suffered the devastating effects of shoulder chondrolysis.

PARTIES

8. Plaintiffs, Gary and Kasha Krol (hereinafter sometimes referred to as "Plaintiffs"), were, at all relevant times, citizens and residents of the State of Ohio, County of Belmont. Plaintiffs, at all times relevant hereto, were and continue to be husband and wife.

9. Defendants Advanced Infusion, Inc., (hereinafter referred to as "Defendants" or "Advanced") is an Arizona corporation with their principal place of business at 290 S Alma School Road #1, Chandler, AZ 85224. At all times relevant hereto, the Defendant was engaged in the testing, manufacturing, labeling, marketing, distributing, promoting and selling of pain pumps in the State of Ohio

10. Service of Process on Advanced Infusion, Inc. may be made outside of this state because they are a nonresident which, acting directly or by an agent, have transacted business in this state; contracted to supply goods in this state; caused tortious injury by acts and/or omissions in this state; and/or caused tortious injury in this state by acts and/or omissions outside this state

while they regularly do business and derive substantial revenue from goods used or consumed in this state.

11. Defendant, Abbott Laboratories (hereinafter referred to as "Abbott"), is an Illinois corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064-3500. Defendant Abbott Laboratories is registered to do business in Ohio. Defendant Abbott is a pharmaceutical company that researches, develops, manufactures and markets generic pharmaceutical products including, but not limited to bupivacaine, lidocaine, and carbocaine, with or without epinephrine. At all times relevant hereto, Abbott was engaged in Ohio, in the testing, manufacturing, labeling, marketing, distributing, promoting, and selling anesthetics.

12. Defendant, Hospira, Inc. (hereinafter referred to as "Hospira"), is a Delaware corporation with its principal place of business at 275 North Field Drive, Lake Forest, Illinois, 60045. Hospira is a pharmaceutical company that researches, develops, manufactures and markets generic pharmaceutical products including, but not limited to bupivacaine, lidocaine, and carbocaine, with or without epinephrine. At all times relevant hereto, Hospira was engaged in Ohio in the testing, manufacturing, labeling, marketing, distributing, promoting, and selling of analgesics.

JURISDICTION AND VENUE

13. The Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332 insofar as the parties are citizens of different states.

14. Venue is proper in this jurisdiction pursuant to 28 U.S.C § 1391(a)(2) because Defendants regularly solicit and engage in business and other persistent courses of conduct and derive substantial revenues from goods used in the State of Ohio. Defendants are corporations maintaining sufficient minimum contacts with this judicial district to subject the corporations to

personal jurisdiction here. Plaintiffs were injured as a result of Defendants' products in Belmont County, Ohio.

15. The amount in controversy in this matter exceeds $75,000.00, exclusive of interest and costs.

FACTUAL ALLEGATIONS

16. Plaintiff, Gary Krol, is a 36 year-old man living in Martin's Ferry, Ohio. Mr. Krol consulted with an orthopedic surgeon for shoulder problems. His orthopedic surgeon, David Tonnies, M.D., recommended surgery for him.

17. On or about May 18, 2004, Mr. Krol underwent shoulder surgery at Sharon Regional Health System Hospital in Sharon, Pennsylvania. Immediately following surgery, Dr. Tonnies affixed subacromially to Mr. Krol's shoulder an Advanced "pain pump" with a continuously injected anesthetic drug, Marcaine®.

18. The anesthetic drug used in the Advanced pain pump during for the May 18, 2004 surgery was 200cc of 0.25% Marcaine® manufactured by Abbott/Hospira.

19. The continuous injection of anesthetic drugs over time directly into her shoulder joint after the May 18, 2004 surgery caused Mr. Krol serious and permanent cartilage damage. As a result, Mr. Krol suffered a narrowing of the joint space and/or a condition called "glenohumeral chondrolysis," which is the complete or nearly complete loss of cartilage in the shoulder joint, an irreversible, disabling, and extremely painful condition. Mr. Krol currently has and will continue to have difficulty doing the most basic tasks of everyday living. He will require additional surgeries, including a shoulder replacement, as a result of the narrowing of the joint space and/or chondrolysis caused by the dangerously defective pain pump and the anesthetics contained therein. His daily life is consumed with the devastation of a destroyed

shoulder and the prospeets of a life of pain and medication. He will suffer lost income, loss of career options, a loss of enjoyment of life and other damages, all of which were avoidable.

COUNT I - NEGLIGENCE
(Advanced Defendant)

20. Plaintiffs ineorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

21. At all relevant times, the Advanced Dcfendant had a duty to exercise reasonable care, and to comply with the existing standard of care, in their preparation, design, research, development, manufacture, inspection, warning, labeling, marketing, promotion, and sale of their pain pumps and the anesthetics used in the pumps, which the Advanced Defendant introdueed into the stream of commerce as effective and safe products, including a duty to ensure that users would not suffer from unreasonable, dangerous or untoward adverse side effects.

22. At all times relevant to this action, the Advanced Defendant had a duty to warn all health care providers and consumers of the risks, dangers, and adverse side effects of pain pumps and the anesthetics used in the pumps.

23. At all times relevant to this action, the Advanced Defeudant knew or reasonably should have known that the pain pumps were unreasonably dangerous and dcfective when used as directed and as designed, including but not limited to the following particulars:

a. Commonly used anesthetics likely to be used in pain pumps were harmful to human and animal articular cartilage and that toxicity to cartilage increased with the duration of exposure;

b. Use of pain pumps with continuously injected anesthetic in the shoulder joint space had not been approved by the FDA, and in fact had been specifically rejected by the FDA;

c. Continuous injection of anesthetic through a catheter, directly into the shoulder, for two days or more, had not been adequately tested for safety or effectiveness; and

d. The risk of narrowing of the joint space, chondrolysis and other serious post-operative problems associated with using pain pumps with continuously injected anesthetic as designed and instructed outweighed the possible benefits of such use.

24. Based on what they knew or reasonably should have known as described above, the Advanced Defendant deviated from principles of due care, deviated from the standard of care, and were otherwise negligent in one or more of the following particulars:

a. In failing to conduct those tests and studies necessary to determine that the use of pain pumps directly into the shoulder was dangerous to shoulder cartilage and contraindicated for use;

b. In failing to instruct or warn the medical community that the safety of the pain pump with continuously injected anesthetic had not been established for use in the shoulder;

c. In failing to disclose to the medical community that continuous injection of commonly used anesthetics such as lidocaine, mepivicaine, or Marcaine®, with or without epinephrine, into the shoulder over two days or more may cause serious and permanent injury to joint cartilage;

d. In failing to include a precaution against placing the catheter of the pain pump in the shoulder;

e. In failing to provide the medical community adequate instructions for the safe use of the deviees with continuously injected anesthetics;

f. In failing to disclose to the medical community that the effectiveness of pain pumps with continuously injected anesthetic was uncertain for use in the shoulder;

g. In failing to disclose to the medical community that no tests had ever been done to determine the safety of using the pain pump in the shoulder;

h. Manufaeturing a product to be used with continuously injected anesthetics, designed to directly inject into the shoulder eommonly used anesthetics assoeiated with damage to articular cartilage.

i. Manufacturing a product designed to deliver, over time, dangerously high doses of anesthetic drugs directly into shoulder tissue; and

j. Promoting pain pumps and continuously injected anesthetics for use in the shoulder joint space after the FDA had considered and rejected such an indication.

25. At all times relevant to this action, the Advanced Defendant knew or reasonably should have known that the anestheties used in the pain pumps were unreasonably dangerous and defective when used as direeted and designed, including but not limited to the following particulars:

a. Commonly used anesthetics likely to be used in pain pumps were harmful to human and animal articular cartilage;

b. Use of pain pumps with continuously injected anesthetic in the shoulder joint space had not been approved by the FDA, and in fact had been specifically rejected by the FDA;

c. Continuous injection of anesthetic through a catheter, directly into the shoulder, for two days or more, had not been adequately tested for safety or effectiveness; and

d. The risk of narrowing the joint spaec, chondrolysis and other serious post-operative problems associated with using pain pumps with continuously injected anesthetic as designed and instructed outweighed the possible benefits of such use.

26. The produet defects alleged above were a substantial contributing cause of the injuries and damages suffered by Plaintiffs that would not have occurred but for the use of the product.

27. The injuries and damages suffered by Plaintiffs wcrc the reasonably foreseeable results of Defendant's negligence.

28. Had the Advanced Defendant performed those tests and studies necessary to determine that pain pumps and their anesthetics should not be used direetly in the shoulder before Mr. Krol's physieian used a pain pump following his surgery, as they were required to do, Mr. Krol would not have developed chondrolysis and Plaintiffs would not have suffered the injuries and damages described with particularity above.

29. As a direct and proximate cause of the Advanced Defendant's negligence, Mr. Krol suffered the permanent loss of cartilage in his shoulder, resulting in severe pain and discomfort of the shoulder and loss of use and function of the shoulder and arm. Mr. Krol will also require future medical care, including physical therapy, pain management, additional

shoulder surgeries as he ages, including but not limited to, shoulder replacement. In addition, Mr. Krol has suffered mental distress and anguish and has suffered permanent impairment of the use and function of his affected upper extremities, and other damages.

COUNT II – NEGLIGENT MISREPRESENTATION
(Advanced Defendant)

30. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

31. The Advaneed Defendant, in the course of its business, negligently misrepresented and failed to diselose material facts concerning the risks their pain pumps and anestheties posed to patients, particularly those using the products for pain relief following shoulder surgery.

32. Mr. Krol and/or his physicians relied upon the Advanced Defendant's misrepresentations for guidance in his decision to select pain pumps following Mr. Krol's shoulder surgery.

33. The false information supplied by the Advanced Defendant to Mr. Krol and/or his physicians was that their pain pumps were safe, effeetive, and would not harm or adversely affect Mr. Krol's health.

34. In making such misrepresentations, the Advaneed Defendant knew or should have known that the representations were false and not completely accurate at the time they made the representations.

35. The concealments, misrepresentations and false information communieated by the Advanced Defendant to Mr. Krol and his physicians were made with the intent to more effectively advertise, market, and sell pain pumps and anesthetics.

36. The concealments, misrepresentations and false information communicated by the Advanced Defendant to Mr. Krol and his physicians were material and Mr. Krol and his physicians justifiably relied in good faith on the Advanced Defendant concealments, misrepresentations and false information, all to Plaintiffs' detriment.

37. As such, the Advanced Defendant failed to exercise reasonable care of competence in obtaining or communicating truthful and accurate information to Mr. Krol and his physician, and failed to comply with the existing standard of care.

38. As a direct and proximate result of the negligent misrepresentations by the Advanced Defendant and their agents and sales representatives, Plaintiffs suffered and will continue to suffer injuries, damages, and losses as alleged and described herein.

COUNT III –
OHIO'S STRICT PRODUCTS LIABILITY ACT, RC 2307.71 TO RC 2307.80
(Advanced Defendant)

39. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

40. The Advanced Defendant placed their pain pumps into the stream of commerce.

41. Mr. Krol was given a pain pump with anesthetic as prescribed by his physicians in a manner that Defendant intended their product to be used.

42. The Advanced Defendant placed its pain pumps into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the product.

43. The Advanced Defendant's pain pumps were defective in design and/or formulation because, when it left the Advanced Defendant's hands, the foreseeable risks exeeeded the benefits associated with the design and/or formulation of the products.

44. The Advanced Defendant's pain pumps were expected to and did reach Plaintiff without substantial change in condition. Alternatively, the pain pumps manufactured and/or supplied by the Advanced Defendant was defective in design, in that when they left the hands of the Advanced Defendant, they were unreasonably dangerous and more dangerous than an ordinary consumer would expect.

45. The pain pump was expected to and did reach Mr. Krol without substantial change in condition. Alternatively, the pain pump manufactured and/or supplied by the Advanced Defendant was defective in design or formulation because with it left the hands of the Advanced Defendant, it was unreasonably dangerous and more dangerous than an ordinary consumer would expect.

46. The Advanced Defendant's pain pump was defective due to inadequate warning and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of such studies.

47. The Advanced Defendant's pain pumps were defective due to inadequate pre- and post-marketing warning or instruction because, after Advanced knew or should have known of the risk of injury from their pain pumps, they failed to provide adequate warnings to the medical community and patients, and continued to promote the products as safe and effective.

48. The pain pumps and anesthetics manufactured, distributed, tested, sold, marketed, advertised and represented defectively by Advanced Defendant, as well as the defective warnings and labeling, were a substantial factor in bringing about the injuries to the Plaintiffs.

49. As the direct and proximate result of the Advanced Defendants' violation of Ohio's Strict Products Liability Act, RC 2307.71 – RC 2307.80, the defective condition of the pain pumps as manufactured and/or supplied by the Advanced Defendants, their failure to warn, and their negligence, carelessness, other wrongdoing and actions described herein, Plaintiffs

suffered and will continue to suffer injuries, damages, and losses as alleged and described herein.

COUNT IV – BREACH OF IMPLIED WARRANTY
(Advanced Defendants)

50. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

51. Plaintiffs purchased and/or ultimately obtained a pain pump from the Advanced Defendant.

52. The Advanced Defendant impliedly warranted that their pain pumps were of merchantable quality and safe and fit for the use for which they were intended.

53. Plaintiffs relied on the skill and judgment and implied warranty of the Advanced Defendant that their pain pumps were of merchantable quality and safe and fit for the use for which they were intended.

54. Contrary to the Advanced Defendant's implied warranty, their pain pumps were not of merchantable quality and not safe nor fit for the use for which they were intended, in that they had serious risks of harm and dangerous propensities when put to their intended use, and would instead cause severe injuries to users of the pain pumps, including Mr. Krol.

55. As a result of the Advanced Defendant's breach of implied warranty, Plaintiffs suffered and will continue to suffer injuries, damages, and losses as alleged and described herein.

COUNT V – NEGLIGENCE
(Defendants Hospira Inc., Abbott Laboratories, "Drug Defendants")

56. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

57. At all times relevant to this action, the Drug Defendants had a duty to exercise reasonable care, and to comply with the existing standards of care, in their preparation, design, research, development, manufacture, usage, inspection, labeling, marketing, promotion and sale of their anesthetics being used in the pain pumps, which said usage the Drug Defendants knowingly marketed and encouraged, including a duty to ensure that users would not suffer from unreasonable, dangerous or untoward adverse side effects.

58. At all times relevant to this action, the Drug Defendants had a duty to warn all health care providers and consumers of the risks, dangers, and adverse side effects of the anesthetics drugs used in the pumps.

59. At all relevant times, the Drug Defendants knew or reasonably should have known that the anesthetics, as used in the pain pumps, were unreasonably dangerous and defective when used as directed and as designed, including but not limited to the following particulars:

a. The commonly used anesthetics likely to be used in pain pumps were harmful to human and animal articular cartilage and that toxicity to cartilage increased with the duration of exposure;

b. Use of pain pumps with continuously injected anesthetic in the shoulder joint space had not been approved by the FDA, and in fact had been specifically rejected by the FDA;

c. Continuous injection of anesthetic through a catheter, directly into the shoulder, for two days or more, had not been adequately tested for safety or effectiveness; and

d. The risk of narrowing of the joint space, chondrolysis and other serious post-operative problems associated with using pain pumps with continuously

injeeted anesthetic as designed and instructed outweighed the possible bcnefits of such use.

60. Based on what they knew or reasonably should have known as described above, the Drug Defendants deviated from principles of due care, deviated from the standard of care, and were otherwise negligent in one or more of the following particulars:

a. In failing to conduct those tests and studies necessary to determine whether the use of pain pumps and their commonly used anesthetics inserted directly into the shoulder was dangerous to shoulder cartilage and contraindicated for use;

b. In failing to instruet or warn the medical community that the safety of the usagc of their continuously injected anesthetic through the pain pump had not been established for use in the shoulder;

c. In failing to disclose to the medical community that continuous injection of commonly used anesthetics such as lidocaine, mepivicaine, or Marcaine® , with or without epinephrine, over two days or more, into the shoulder, may cause serious and permanent injury to the joint cartilage;

d. In failing to provide to the medical community adequate instructions for the safe use of the their continuously injected anesthetics in conjunction with pain pumps;

e. In failing to disclose to the medical community that the effectiveness of their continuously injected ancsthetic with pain pumps anesthetic was uncertain for use in the shoulder;

f. In failing to disclose to the medical community that no tests had been ever done to determine the safety of using continuously injected anesthetics in conjunction with a pain pump in the shoulder;

g. Promoting usage of a continuously injected anesthetie in a product designed to directly inject into the shoulder said anesthetics associated with damage to articular cartilage and;

h. Promoting usage of a continuously injected anesthetic for usage in a product, speeifically pain pumps, in the shouldcr joint space after the FDA had considered and rejected such an indication.

61. At all relevant times, the Drug Defendants knew or reasonably should have known that the anesthetics used in the pain pumps were unreasonably dangerous and defective when used as directed and designed, including but not limited to thc following particulars:

a. Commonly used anesthetics likely to be used in pain pumps were harmful to human and animal articular cartilage;

b. Use of pain pumps with continuously injected anesthetic in the shoulder joint space had not been approved by the FDA, and in fact had been specifically rejected by the FDA;

c. Continuous injection of anesthetic through a catheter, directly into the shoulder, for two days or more, had not been adequately tested for safety or effectiveness; and

d. The risk of narrowing of the joint space, chondrolysis and other serious post-operative problems associated with using pain pumps with continuously injected anesthetic as designed and instructed outweighed the possible benefits of such use.

62. The defects alleged above were a substantial contributing cause of the injuries and damages suffered by Plaintiffs that would not have occurred but for the use of the anesthetics.

63. The injuries and damages suffered by Plaintiffs were the reasonably foreseeable results of the Drug Defendants' negligence.

64. Had the Drug Defendants performed those tests and studies necessary to determine that their anesthetics should not be used directly in the shoulder before Mr. Krol's physician used a pain pump following his surgery, as they were required to do, Mr. Krol would not have developed chondrolysis and Plaintiffs would not have suffered the injuries and damages described with particularity, above.

65. As a direct and proximate cause of the Drug Defendants' negligence, Mr. Krol suffered the permanent loss of cartilage in his shoulder, resulting in severe pain and discomfort of the shoulder, loss of use and function of the shoulder and arm. Mr. Krol will also require future medical care, including physical therapy, pain management, additional shoulder surgeries as he ages, including but not limited to, shoulder replacement. In addition, Mr. Krol has suffered mental distress and anguish and has suffered permanent impairment of the use and function of his affected upper extremities, and other damages. Plaintiffs have and will continue to suffer injuries, damages, and losses as alleged and described herein.

COUNT VI –
OHIO'S STRICT PRODUCTS LIABILITY ACT, RC 2307.71 TO RC 2307.80
(Defendants Hospira Inc., Abbott Laboratories, "Drug Defendants")

66. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

67. The Drug Defendants placed their anesthetic into the stream of commerce.

68. Mr. Krol was given the anesthetic as prescribed by his physicians in a manner that the defendants intended their products to be used.

69. The Drug Defendants placed its anesthetic into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

70. The anesthetic was defective in design and/or formulation because, when it left the Drug Defendants' hands, the foreseeable risks of use following shoulder surgery exeeeded the benefits associated with the design and/or formulation.

71. The anesthetic was expected to and did reach Plaintiffs without substantial change in condition. Alternatively, the anesthetic manufactured and/or supplied by the Drug Defendants was defective in design or formulation because when it left the hands of the manufacturing drug defendants, it was unreasonably dangerous and more dangerous than an ordinary cousumer would expect.

72. The anesthetic drug was defective due to inadequate warning and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of such studies.

73. The anesthetic drug was defective due to inadequate pre- and post-marketing warning or instruction because, after the Drug Defendants knew or should have known of the risk of injury from their products, they failed to provide adequate warnings to the medical community and patients, and continued to promote the products as safe and effective.

74. The anesthetics manufactured, distributed, tested, sold, marketed, advertised and represented defectively by the Drug Defendants was a substantial factor in bringing about the Plaintiffs' injuries that would not have occurred but for the use of the product.

75. As a direct and proximate result of the Drug Defendants' violation of Ohio's Strict Products Liability Act, RC 2307/71 – RC 2307.80, the defective condition of the Drug Defendants' product, the Drug Defendants' failure to warn, and their negligence, carelessness,

other wrong doing and actions described herein, Plaintiffs suffered and will continue to suffer injuries, damages, and losses as alleged and described herein.

COUNT VII – BREACH OF IMPLIED WARRANTY
(Defendants Hospira Inc., Abbott Laboratories, "Drug Defendants")

76. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

77. Plaintiffs purchased and/or ultimately obtained an anesthetic, Marcaine®, from the Drug Defendants.

78. The Drug Defendants impliedly warranted that their anesthetic, Marcaine®, was of merchantable quality and safe and fit for the use for which it was intended.

79. Plaintiffs relied on the skill and judgment and implied warranty of the Drug Defendants that their anesthetic was of merchantable quality and safe and fit for the use for which it was intended.

80. Contrary to the Drug Defendants' implied warranty, their anesthetic was not of merchantable quality and was neither safe nor fit for the use for which it was intended, in that it had serious risks of harm and dangerous propensities when put to its intended use, and would instead cause severe injuries to users of the anesthetic, including Mr. Krol.

81. As a result of the Drug Defendants' breach of implied warranty, Plaintiffs suffered and will continue to suffer injuries, damages, and losses as alleged and described herein.

COUNT VIII– LOSS OF CONSORTIUM
(All Defendants)

82. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

83. Plaintiffs, at all times relevant hereto, were and continue to be husband and wife.

84. Plaintiff, Kasha Krol, as a result of the injuries sustained by Plaintiff, Gary Krol, deseribed above, has suffered loss of consortium. She has suffered, and will eontinue to suffer in the future, mental anguish, the loss of support, love, companionship, affection, society, sexual relations, solace and other damages.

85. In addition, the marital association between Mr. and Mrs. Krol has been damaged.

86. Accordingly, Plaintiff Kasha Krol seeks and is entitled to compensatory damages in an amount to be determined at trial.

COUNT IX – PUNITIVE DAMAGES
(All Defendants)

87. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth hcrcin.

88. Plaintiffs are entitled to punitive damages because the Defendants' conduct and failure to warn was intentional, wanton, willful and/or outragcous, and said conduct was committed with gross negligence, reckless disregard of, and deliberate, callous and reckless indifference to Plaintiffs' rights, interests, welfare and safety. The Defendants misled both the medical community and the public at large, including the Plaintiffs herein, by making false representations about the safety of their products. The Defendants downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects associated with the use of their products despite available information demonstrating these products were likely to cause serious side effects to the users.

89. The Defendants were or should have been in possession of evidence demonstrating that their products caused serious side effects. Nevertheless, they continued to market the products by providing false and misleading information with regard to safety and efficacy.

90. Defendants failed to provide warnings that would have dissuaded medical providers from using the pain pumps and anesthetics thus depriving medical providers and consumers from weighing the true risks against the benefits of using these products.

91. As a direct and proximate result of these breaches Mr. Krol was caused to be exposed to pain pumps and anesthetics after her shoulder surgery, thereby causing the injuries described more fully herein.

92. As a result of the foregoing, Plaintiffs are entitled to punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants as follows:

1. Economic and non-economic damages and damages for pain and suffering and loss of basic and pleasurable activities in an amount in excess of $75,000 as provided by law and to be supported by the evidence at trial;

2. For compensatory and other damages according to proof;

3. For punitive damages according to proof;

4. For disgorgement of profits;

5. For an award of attorneys' fees and costs;

6. For prejudgment interest and the costs of suit; and

7. For such other and further relief as this Court may deem just and proper.

JURY DEMAND

A trial by jury before the maximum number of jurors allowed by law is hereby demanded.

Dated: November 24, 2009

Respectfully submitted,

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VERIFICATION

I, Gary Krol, do hereby certify and swear under penalty of perjury that the factual information set forth in the foregoing Complaint, is true and correct, to the best of his knowledge and belief, the undersigned certifies and verifies as aforesaid that he verily believes the same to be true and that the undersigned has reviewed the Complaint.

Gary Krol

STATE OF WEST VIRGINIA;
COUNTY OF OHIO, to-wit:

I, Angela Britton, a Notary Public in and for the State and County aforesaid do hereby certify that Gary Krol, whose name is signed in the foregoing Complaint bearing the date of the 23rd day of October, 2009, has this day acknowledged the same before me in my said county.

Given under my hand this 23rd day of October, 2009.

My commission expires October 31, 2015.

Notary Public

OFFICIAL SEAL
NOTARY PUBLIC
STATE OF WEST VIRGINIA
ANGELA BRITTON
R.D. #3, Box 192X
Wheeling, West Virginia 26003
My Commission Expires Oct. 31, 2015